



QUALITY ASSURANCE AUDITS AND MANAGEMENT ASSESSMENTS

Quality Implementing Procedure ID: OSTI-LBNL-QIP-18.0, Rev. 0, Mod. 0

Effective: 05/07/04

1. PURPOSE

This Quality Implementing Procedure (QIP) establishes the responsibilities and process for scheduling, planning, performing, documenting, and responding to internal audits of the Office of Science & Technology and International (OSTI)-Lawrence Berkeley National Laboratory (LBNL) Project activities, and external audits of suppliers of quality-related services, as needed. The OSTI-LBNL Project has requested the U.S. Department of Energy (DOE) Office of Civilian Radioactive Management (OCRWM) Office of Quality Assurance (OQA) to perform OSTI-LBNL internal and external audits as documented in the *OSTI-LBNL Quality Assurance Plan*.

This procedure also establishes the requirements for the performance of management assessments by personnel outside the OSTI-LBNL Project to assess the adequacy and effectiveness of the OSTI-LBNL QA Program and the implementation thereof.

2. SCOPE

This QIP has been prepared in accordance with OSTI-LBNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*, and applies to all OSTI-LBNL Project activities subject to the DOE OCRWM *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P.

This QIP applies to the Quality Assurance (QA) Manager, the Project Manager (PM), the Deputy PM, and all OSTI-LBNL audited participants during the audit process conducted by OQA.

3. PROCEDURE

3.1 Scheduling Internal Audits

The purpose of planned and scheduled internal audits is to verify compliance and performance of OSTI-LBNL Project activities with all aspects of the OSTI-LBNL QA Program and to determine the adequacy and effectiveness of the OSTI-LBNL QA Program.

3.1.1 Project Manager (PM):

- A. Provide the QA Manager with *Guidance and Funds to Lawrence Berkeley National Laboratory for Tasks from the OCRWM* memoranda and any pertinent supporting information as background for determining an audit schedule.

- B. Direct the QA Manager to prepare an appropriate Annual Internal Audit Schedule for quality-related (Q) tasks. Non-Q tasks may also be audited per the direction of the PM

3.1.2 QA Manager:

- A. Prepare an Annual Internal Audit Schedule and audit scope as directed, or as a minimum, before the start of each fiscal year (FY) considering the following:

- Internal audits shall be scheduled in a manner to provide coverage, consistency, and coordination with ongoing work.
- Internal audits shall be scheduled at a frequency commensurate with the status and importance of the work.
- Internal audits shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work.
- Regularly scheduled internal audits shall be supplemented by additional audits or surveillance of specific subjects, when necessary, to provide an adequate assessment of compliance or effectiveness or when requested by the PM or Principal Investigator (PI) of the area to be evaluated.
- Internal audits of work to verify OSTI-LBNL QA Program compliance shall be performed at least once during the life of the work. The maximum period between compliance-based audits shall be 15 months.
- Internal audits to determine OSTI-LBNL QA Program effectiveness and product adequacy (performance-based audits) shall be performed on selected work.

In determining the audit scope, the QA Manager considers audit schedules, monthly progress reports, the work being audited, results of previous audits or surveillances of the audited task, and the impact of significant changes in personnel, the OSTI-LBNL organization, or OSTI-LBNL QA Program. The scope of an audit can include evaluation of product quality or of the technical adequacy of work, as appropriate, as well as programmatic compliance and implementation effectiveness. Technical requirements may be selected for audit evaluation from the governing OSTI-LBNL Technical Work Plans, associated QIPs, and Technical Implementing Procedures (TIPs).

- B. For each proposed internal audit, the QA Manager shall provide the following information on a preliminary Annual Internal Audit Schedule:
- Audit number (e.g., OSTI-LBNL-04-C-001)

- where 04 = last two digits of FY
- C = Compliance; P = performance based (as defined in Section 6.2)
- 001 = sequential number within the year
- Task to be audited
- Proposed dates for the audit
- Audit type and scope

C. The schedule shall be submitted to the Deputy PM for review and the PM for concurrence.

3.1.3 PM

- A. Review and approve the annual audit schedule (and any revisions thereof).
- B. Direct the QA Manager to develop revisions to the audit schedule as necessary to ensure that coverage is current and that audit requirements are met.

3.1.4 QA Manager:

- A. Submit the schedule to OCRWM OQA, solicit their input, make revisions as directed by OQA (e.g., incorporate OQA audit numbering system) and coordinate with OQA the schedule for performance of requested audits per the requirements of Section 18 of the QARD.
- B. Submit the approved Annual Audit Schedule (and any revisions thereof) to the Records Coordinator for submittal to the Records Processing Center (RPC) per Section 4.0.

3.2 Audit Participation

3.2.1 QA Manager (or designee):

- A. Serve as the OSTI-LBNL lead Point of Contact and facilitate audit activities between the OQA audit team and OSTI-LBNL staff members, keep abreast of potential issues identified during the course of the audit, and inform the PM, Deputy PM and affected OSTI-LBNL Staff accordingly.
- B. Participate in management debriefings and coordinate any corrective actions to findings that can be resolved during the course of the audit to the satisfaction of the audit team.

3.2.2 PM (or designee)

Participate in audit debriefings, provide guidance as needed, and direct that corrective actions be implemented where possible during the course of the audit.

3.2.3 Audit Participants:

Provide cooperation and timely responses to auditor questions, keep the PM, Deputy PM and QA Manager abreast of possible audit findings, and perform corrective actions during the course of the audit as directed by the PM (or designee) and/or the QA Manager.

3.3 Responding to Audits

3.3.1 PM (or designee)

Upon receipt of an audit report, ensure that an investigation is conducted to any identified conditions adverse to quality by the QA Manager and affected PIs or Responsible Individuals, ensure the adequacy of the OSTI-LBNL response to audit findings, and ensure the adequacy of corrective action implementation thereof.

3.3.2 QA Manager (or designee):

- A. Coordinate audit responses with affected Principle Investigators (PIs) or Responsible Individuals, collectively determine immediate actions, remedial actions, cause, measures to prevent recurrence, and estimated completion dates for these actions per directions provided by OQA.
- B. Prepare the complete audit response and notify OQA in writing of the actions taken or planned.
- C. Oversee that appropriate actions are taken by affected PIs or Responsible Individuals in a timely manner, and notify OQA upon the completion thereof.

3.3.3 PI or Responsible Individual

Prepare responses, together with the QA Manager, as directed by the PM, perform corrective actions, as appropriate, in a timely manner, notify the QA Manager upon completion of actions taken and provide documented evidence of the completion thereof.

3.3 Scheduling External Audits

Should OSTI-LBNL require the use of a supplier not on the OCRWM Qualified Suppliers List (QSL), the **QA Manager**, with the concurrence of the PM, shall request OCRWM OQA to perform audits thereof per the requirements of Section 18 of the QARD. The OSTI-LBNL Project shall not use any suppliers for quality related service that have not been qualified on the OQA QSL

3.5 Scheduling Management Assessments

The PM shall request the performance of management assessments of the OSTI-LBNL Project by OCRWM or another independent organization annually. The management assessment shall evaluate the:

- A. Adequacy of resources and personnel provided to achieve and assure quality.
- B. Adequacy of the OSTI-LBNL-QA Program.
- C. Effectiveness of the OSTI-LBNL QA Program.

The Management Assessment shall be documented and directed to the PM, and be distributed to the Deputy PM, QA Manager and other affected OSTI-LBNL staff as deemed appropriate. Measures for improvement of the OSTI-LBNL QA Program shall be considered and implemented per the direction of the PM, together with the QA Manager, based on results of the assessment, as appropriate.

4. RECORDS

Records identified below shall be submitted to the RPC in accordance with OSTI-LBNL-QIP-17.0, *Records Management*. Audit-related records are submitted by OQA to the RPC as specified in the governing OQA audit procedure.

4.1 QA Records

Individual

Approved Annual Audit Schedules and revisions thereof

4.2 Non-QA Long-Term Records

Management Assessment –related documentation

4.3 Non-QA Short Term Records (three years or less retention)

None.

5. RESPONSIBILITIES

- 5.1 The **Project Manager (PM)** (or designee) is responsible for directing the QA Manager to develop an annual audit schedule of OSTI-LBNL activities, for providing appropriate background information, for approving the schedule, participating in audit briefings, and ensuring adequate corrective actions are implemented per the direction of OCRWM OQA. The PM also requests an independent organization to perform a

management assessment of the adequacy of the OSTI-LBNL QA Program and the effectiveness thereof.

- 5.2** The **Deputy PM** is responsible for reviewing the Annual Audit Schedule, and providing general guidance to line and QA staff during the course of the audit process.
- 5.3** The **Quality Assurance (QA) Manager** is responsible for preparing the Annual Audit Schedule and revisions thereof, requesting and coordinating OCRWM OQA to perform internal (and external) audits of OSTI-LBNL Project activities, serving as the Point of Contact during the audit, and coordinating OSTI-LBNL responses and corrective actions to audit findings.
- 5.4** **OSTI-LBNL Audit Participants** are responsible for providing cooperation and assistance to auditors during the course of audits, preparing responses as directed, and performing adequate corrective actions to the satisfaction of OQA.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

DOE	U.S. Department of Energy
LBNL	Lawrence Berkeley National Laboratory
PI	Principal Investigator
PM	Project Manager
Q	quality-related
QA	Quality Assurance
QARD	Quality Assurance and Requirements Document
OCRWM	Office of Civilian Radioactive Waste Management
OQA	Office of Quality Assurance
OSTI	Office of Science & Technology and International
QIP	Quality Implementing Procedure
QSL	Qualified Suppliers List
RPC	Records Processing Center
TIP	Technical Implementing Procedure
TWP	Technical Work Plan

6.2 Definitions

Compliance-Based Audit: An audit methodology used to determine through investigation of objective evidence the adequacy of and compliance with established implementing documents and overall effectiveness of implementing QA Program requirements.

Internal Audit: A verification activity performed as a Compliance-Based Audit or a Performance-Based Audit.

Performance-Based Audit: An audit methodology in which processes or activities are evaluated based upon their expected results to allow subsequent conclusions about the

adequacy of the products, and the adequacy and effectiveness of the processes or activities associated with those products.

Management Assessment: A QA program verification that is conducted by management above or outside the QA organization and that evaluates the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the QA program (QARD).

7. REFERENCES

DOE/RW-0333P, *Quality Assurance Requirements and Description*

OSTI-LBNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*

OSTI-LBNL-QIP-17.0, *Records Management*

8. ATTACHMENTS

None.

9. REVISION HISTORY

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Initial issue.

10. APPROVALS

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